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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,521	09/08/2003	Anne Marie Chalmers	AIIJ-001	5731

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LAHIVE & COCKFIELD, LLP.  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER

TRAN, SUSAN T

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/657,521

Applicant(s)

CHALMERS, ANNE MARIE

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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**DETAILED ACTION*****Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6-12 of copending Application No. 10/690,387 ('387). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '387 application claims a device for the simultaneous delivery of multiple medication products to a live body comprising a first, second, and third containment means. The '387 application does not expressly teach the first, second, and third containment means are alternatively containing within each other. However, the broad teaching of the claims that the first, second, and third containment means are affixed to each other without any further limitations, allow the containment means to affixed within each other. Accordingly, it would have been obvious to one of ordinary skill in the art to affix the

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containment means of the '387 application by placing them inside each other and still be able to connect them with an affixing means to obtain the claimed invention. There are no unusual and/or unexpected results which would rebut prima facie obvious. As such, the instant claims would have been obvious given the claims of the '387 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/787,278 ('278). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '278 application claims a device for the simultaneous delivery of multiple medication products to a live body comprising a first, and second containment means. The '278 application does not expressly teach the first, and second containment means are alternatively containing within each other. However, the broad teaching of the claims that the first, and second containment means are affixed to each other without any further limitations, allow the containment means to affixed within each other. Accordingly, it would have been obvious to one of ordinary skill in the art to affix the containment means of the '278 application by placing them inside each other and still be able to connect them with an affixing means to obtain the claimed invention. There are no unusual and/or unexpected results which would rebut prima facie obvious. As such, the instant claims would have been obvious given the claims of the '278 application.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sanso US 6,350,468.

Sanso discloses a pharmaceutical dosage form comprising an internal capsule placed inside an external capsule, wherein each capsule includes one or more active agent (see abstract; examples; and claims 22+).

Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Digenis et al. US 5,672,359.

Digenis discloses a hard capsule comprising three or more distinct compartments (inner, intermediate, and outer), wherein each compartment comprises a drug or an active agent (see abstract; column 4, lines 54 through column 5, lines 1-47).

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Claims 2, 4, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Aebischer et al. US 5,182,111.

Aebischer discloses a delivery device comprising at least one biologically active factor encapsulated within a biocompatible membrane (see abstract; and column 6, lines 18-64). The device can be in any shape including multi-capsules and multi-compartment capsules, wherein each compartment comprises active factors encapsulated in a biocompatible membrane which can be in any shape, such as capsule, macrocapsule, or microcapsule (column 5, lines 4-17; and column 7, lines 54-59; and Figures 8 and 9).

Claims 1, 3, 5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Miller et al. US 2003/0194430 A1.

Miller discloses a multi-compartment capsule comprising a primary capsule housing a secondary capsule and the secondary capsule housing a tertiary capsule, wherein each capsule include one or more active agents or medicaments (see Fig. 2 and 13; paragraphs 0041, 0059 and 0060).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. US 2003/0194430 A1.

Miller teaches a multi-compartment capsule comprising a primary capsule housing a secondary capsule and the secondary capsule housing a tertiary capsule, wherein each capsule include one or more active agents or medicaments (see Fig. 2 and 13; paragraphs 0041, 0059 and 0060). Miller further teaches a single dosage capsule comprising a plurality receiving chambers having an internal periphery for introducing a secondary capsule (see Figs. 6 and 8; paragraphs 0047, 0064-0066, and 0073-0075). Miller does not explicitly teach a tertiary capsule in one of the plurality receiving chambers. However, it is the position of the examiner that it would have been obvious to one of ordinary skill in the art to, by routine experimentation introducing a tertiary capsule into one of the plurality receiving chambers to obtain the claimed invention, because Miller teaches that the components as generally described and illustrated in the Figures could be arranged and designed in a wide variety of different configurations (paragraphs 0053), and because Miller suggests and recognizes placing a tertiary capsule into the multi-compartment capsule (see Figures 2 and 13).

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Claims 2, 4, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. US 2003/0194430 A1, in view of Aebischer et al. US 5,182,111.

Miller is relied upon for the reason stated above. Miller does not explicitly teach a tertiary capsule in one of the plurality receiving chambers.

Aebischer discloses a multi-compartment delivery device comprising different cells (Figures 8 and 9). Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule of Miller using the multi-compartment capsule in view of the teaching of Aebischer, because Aebischer teaches a multi-compartment capsule housing three individual compartments (see Figures 8), because Aebischer teaches the capsule provides more reliable or more potent therapy useful for the sustained and controlled release of active agent (column 2, lines 52-59), and because Miller teaches a multi-compartment capsule that exhibits various desirable properties including, controlling time release, prolonging shelf-life, and reducing the number of capsules consumed by a patient (paragraphs 0022).

### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Glassman, Wong et al., and Azalbert are cited as of interest for the teaching of multi-compartment capsule.

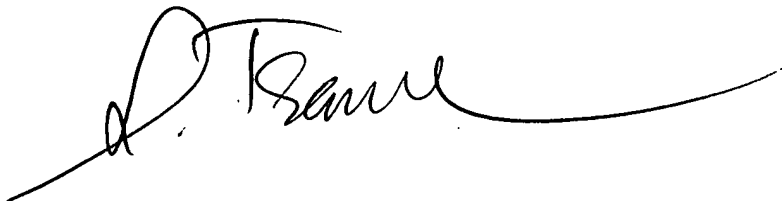
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***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'S. Tran', with a long horizontal flourish extending to the right.

S. Tran  
Patent Examiner  
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